an end cap removably covering an end of the cartridge that includes the single orifice; and

[further including] a plurality of [plastic material] gaps, formed in the thickness of the [plastic overmould of] envelope molded over the cartridge [(28)], in order to produce slots [(63)] for improving the visibility of the [first element (49)] receptacle.

--13. In a needle-free single use injection device of a pharmaceutical product, the device having a cap relatively movable relative to a device body for triggering a percussion member contained in the body, a cartridge mounted to an end of the device opposite the cap, the cartridge containing the product and driven by the percussion member, and the cartridge comprising:

a receptacle of preselected material and containing a single use quantity of the pharmaceutical product;

a single orifice formed in the receptacle for providing an exit for a jet of injected pharmaceutical product;

an envelope made of a preselected material and covering the receptacle; and

an end cap removably covering an end of the cartridge that includes the single orifice.

REMARKS

The Office Action has been carefully considered. In an effort to expedite the prosecution of the present application, changes have been made to the drawings so as to avoid further objection by the Examiner. Further, the specification has been amended to clarify the points raised by the Examiner. Finally, the claims have been amended to more clearly set forth the invention as compared to the cited prior art.

The following points will relate to the objection of the drawings as stated in paragraphs 1-7 (pages 2-3) of the Office Action. Concerning paragraph 2, annular

guide 17a has been added to the specification on page 5, line 20. Slot 8a is now mentioned on page 6, line 15.

In paragraphs 3 and 4, the Examiner requires an indication of cap 55. This has been shown on Fig. 9.

In paragraph 5 of the Office Action, the Examiner objects to Figs. 1 and 2 of the drawings since they alternatively show a ring and a knurled wheel. Although Figs. 1 and 2 are views of the present injection device before and after triggering, the means for adjusting the tension of spring 18 can alternately be a knurled wheel 46 (Fig. 1) or a washer stack arranged between spring 18 and ring 25 (Fig. 2). This alternative detail has been added by the foregoing amendment to page 4, lines 28-32. If the Examiner requires it, additional dotted lines showing both variations could be added to Figs. 1 and 2, but it is believed that such an addition would confuse matters. A simple explanation as entered by the amendment to page 4 certainly clarifies the alternate use of the ring or wheel. In paragraph 5 of the Office Action, the Examiner further questions Applicants' mention of "orifice 61" (page 9, line 32). The aforementioned amendment corrects this reference so that it is now correctly mentioned as "recess 61".

In paragraph 6 of the Office Action, the Examiner questions Applicants' use of reference numerals "14" and "20". The foregoing amendment to page 5, line 21, correctly refers to reference numeral 20 as the peripheral surface of the clamp 8.

Concerning the objections to the drawings as stated in paragraph 7 of the Office Action, reference numeral "41" now correctly illustrate the raised zones. Regarding reference numeral "31", Applicants have amended page 8, line 37, to correctly indicate that the outlet orifice should be reference numeral 29.

The Examiner's comments concerning the specification have been reviewed. The points raised by the Examiner in paragraph 8 of the Office Action have been attended to so as to avoid confusion.

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In paragraph 9 of the Office Action, the Examiner objects to the specification as failing to adequately provide an enabling disclosure. The operation of the safety device 47 shown in Fig. 9 has been elaborated in the specification — on page 5, line 10. No new matter is introduced. Instead, the inherent operation of the part shown in Fig. 9 is briefly discussed.

In summary, the aforementioned explanation is believed to dispose of the objections to the specification and the drawings.

Claims 1-12 have been objected to and rejected under 35 U.S.C. § 112, as failing to clearly define the invention. Claims 8-11 have been indicated as being allowable if rewritten to overcome the § 112 rejection. These claims have been amended so as to clearly set forth the patentable subject matter therein. Accordingly, formal allowance of claims 8-11 is in order.

Claims 1-5 were rejected under 35 U.S.C. § 102(b), as anticipated by Colavecchio (U.S. Patent No. 5,256,142). Independent claim 1 has been replaced by claim 13 which sets forth the novel structure of a single-use cartridge employed by an injection device. In contrast to the claimed invention, Colavecchio is directed to an injector that uses a one-shot cap 10. The cap is basically a hygienic device which contacts a person's skin, the cap being fitted to the head of the injector. As explained in col. 3, lines 1-7, the one-shot cap includes a preestablished breaking zone which breaks after injection, thereby making it impossible to reuse the cap. The medicament is actually contained within an orthogonally mounted phial 31. As explained in col. 4, lines 46-50, the injector meters an exact quantity of medicament through needle 30, from phial 31. Therefore, the phial receptacle of the medicament contains more than a single use quantity.

Independent claim 13 is directed to an injection device single-use cartridge. The cartridge itself includes a receptacle containing a single-use quantity of a pharmaceutical product. The receptacle includes an orifice for providing an exit for a

jet of injected pharmaceutical product. After expulsion of all the pharmaceutical product contained in the receptacle, the cartridge must be removed and replaced with a new cartridge. Structurally, the cartridge includes an envelope that covers the receptacle for providing structural integrity and means for mounting the cartridge to the injector device. On page 7, paragraph 14, of the Office Action, the Examiner considers the Colavecchio device to have a cartridge including a first glass element 16 for containing medicament and a second plastic element 10 that surrounds the glass container 16. However, as clearly shown in Fig. 1 of the reference and explained in the specification, element 16 is an injector head (cross-hatched in Fig. 1 as metal). The head does not contain the medicament in the same manner as the claimed receptacle of claim 13. Therefore, in summary, independent claim 13 is directed to a cartridge configuration that has no comparable structure in the cited reference.

Dependent claims 2-5 further differentiate the claimed invention from the cited prior art. Claim 2 specifies that the receptacle is made from medical-grade glass. As pointed out above, the Colavecchio device head 16 is cross-hatched for metal — not glass. Dependent claim 3 specifies that an envelope moulded over the receptacle is fabricated from a plastic material having particular characteristics. The one-shot cap 10 of Colavecchio covers the injector head 16 and not the receptacle 31, as is required by the claimed invention. Regarding claim 4, there is a specific relationship between the diameter of a percussion rod and the inlet and outlet orifices of the cartridge. In Colavecchio, the percussion rod may have relationships to head 19 but not to the receptacle 31. In claim 5, engagement means are recited for fixing the cartridge to the end of the injection device. In Colavecchio, the receptacle and, thus, cartridge 31 are orthogonally secured to the side of the injector device. The breakable one-shot cap 10 cannot be considered a cartridge since it does not normally contain a charge of medicament.

On page 8 of the Office Action, claims 1-7 were rejected under 35 U.S.C. § 103, as being unpatentable over GB 677,523 in view of Colavecchio. The British reference is directed to a hypodermic injection device utilizing a medicament-containing cartridge. An important consideration of the reference is the inclusion of plural injection orifices (col. 1, lines 40-44, and col. 3, lines 37-43). In marked contrast, independent claim 13 specifies that the receptacle includes a single orifice providing an exit for a jet of injected pharmaceutical product. Aside from this significant difference, the combination of the British reference and Colavecchio is most unlikely since the former deals with a multi-use side mounted receptacle 31, while the latter is directed to a hypodermic needle using an in-line cartridge. To combine the references, one would have to completely redesign both devices so as to resemble and function in a manner similar to that of the claimed invention. This is simply beyond one having ordinary skill in the art and could only be constructed with total reliance upon hindsight. Therefore, the combination of references fails to present a *prima facie* case of obviousness.

The unlikely combination of the references further renders dependent claims 2-7 allowable. It should be pointed out that dependent claims 6 and 7 present structural limitations in their own right that are not met by the references.

Claims 1 and 12 were rejected under 35 U.S.C. § 103(a), as being unpatentable over Colavecchio in view of Stiehl. The Examiner relies on the latter reference for its teaching of a viewing window 26 formed in a plastic holder. Although this feature, *per se*, is not deemed to be patentable, its inclusion with the cartridge structure set forth in claim 13 is believed to distinguish the combined structure from the unlikely combination of Colavecchio and Stiehl. The combination of references is unlikely since Colavecchio is directed to an injector device having a side mounted receptacle 31 which meters a dose of medicament into the injector head 16. This is in marked contrast to the hypodermic syringe shown in Stiehl. It would hardly be obvious to one

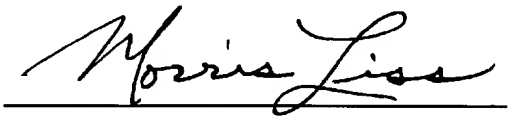
of ordinary skill in the art to modify the head and receptacle portions of Colavecchio to accommodate a hypodermic in-line configuration, as shown in Stiehl. Therefore, this combination of references does not present a *prima facie* case of obviousness.

For the reasons set forth above, claims 8-11, previously indicated as containing allowable subject matter, have been amended so as to be formally allowable. The remaining amended claims are believed to be distinguishable over the prior art. Therefore, reconsideration of the application, and favorable Action thereon, are courteously solicited.

DEPOSIT ACCOUNT AUTHORIZATION

It is not believed that extensions of time or fees for net addition of claims are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary, then such extensions of time are hereby petitioned under 37 CFR § 1.136(a), and any fees required for consideration of this paper, including fees for net addition of claims, are hereby authorized to be charged to our Deposit Account No. 22—0185.

Respectfully submitted,



Morris Liss, Reg. No. 24,510
Pollock, VandeSande & Priddy
1990 M Street, N.W.
Washington, D.C. 20036-3425
Telephone: 202-331-7111

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